



Defense Federal Acquisition Regulation (DFAR)

Human Subject Protection Clause



An Introduction and Overview for Contracting Offices Supporting the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD/P&R)



Overview

- Defense Federal Acquisition Regulation (DFAR) Citation
- Introduction to the Human Research Protection Program (HRPP)
- Interaction of HRPP & DFAR Requirements
- Authorities and Responsibilities



Defense Federal Acquisition Regulation Supplement (DFARS) Status



- DoD amended the Defense Federal Acquisition Regulation Supplement (DFARS) to address requirements for the protection of human subjects involved in research projects.
- The new rule contains a clause for use in contracts that include or may include research involving human subjects.



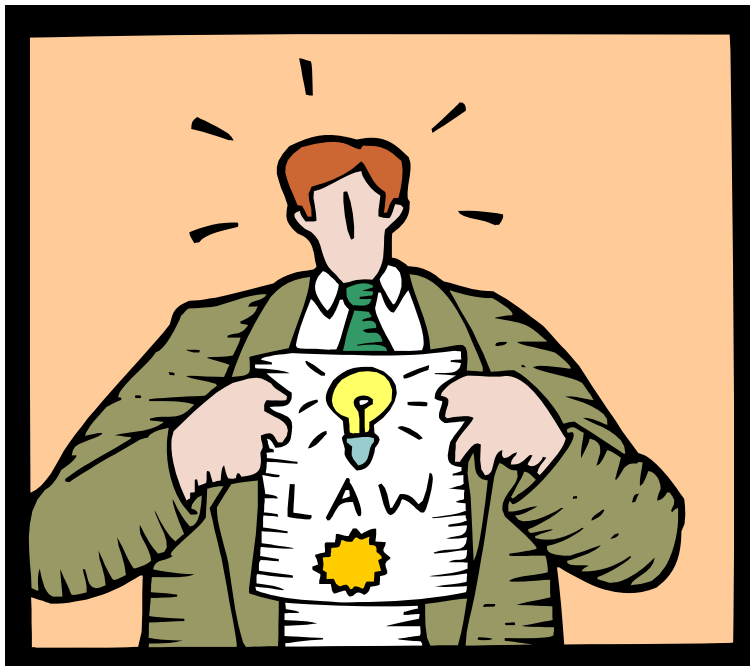
Defense Federal Acquisition Regulation Supplement (DFARS) Citation



- [Published in the Federal Register \(FR\) 29 July 2009](#)
- 48 CFR Parts 207, 235, and 252. This clause should only apply to a small percentage of DoD contracts; however, failing to follow the rule when it does apply can have serious consequences.



DFARs Supplement Status



- Although this DFARS Clause was **enacted** recently, the underlying requirement is not new.
- The Clause simply reinforces current regulations by adding procedures on how to apply the requirements within the acquisition framework.



Research Related Definitions

32 Code of Federal Regulations (CFR) Part 219.102:

- Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains:
 - (1) Data through intervention or interaction with the individual,
 - OR
 - (2) Identifiable private information.



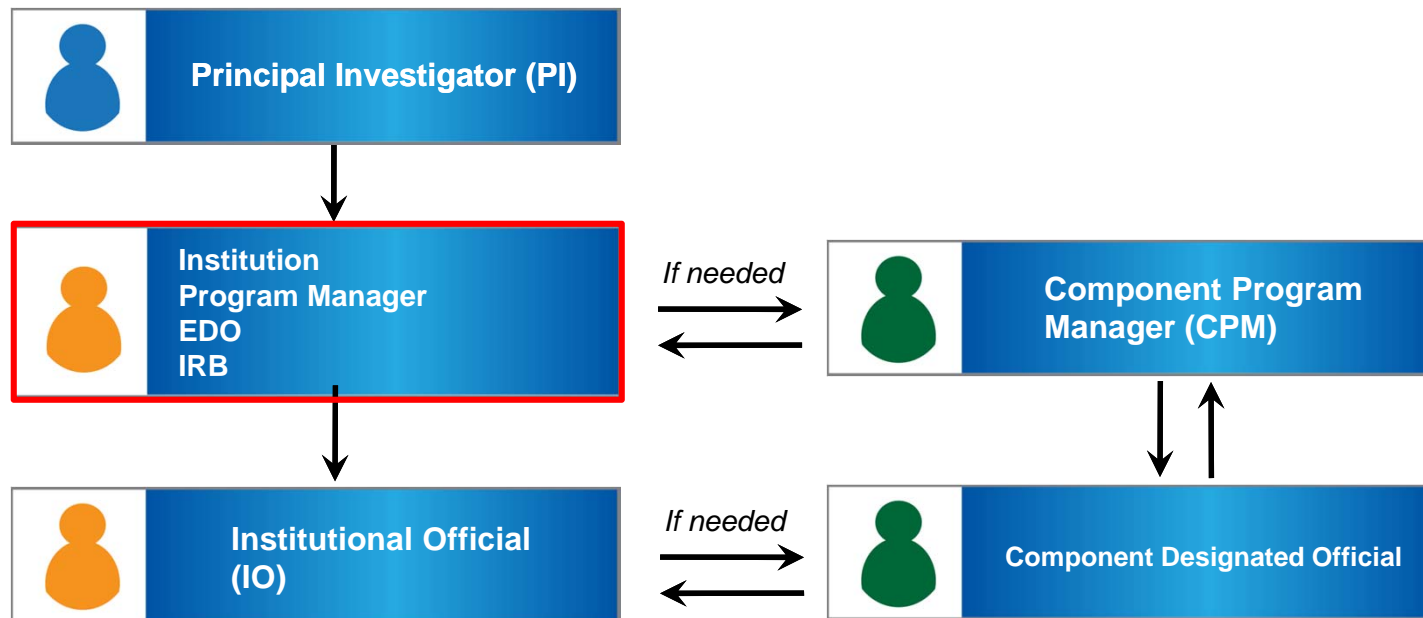
Research Related Definitions

32 CFR 219.102:

- Intervention: includes both physical procedures by which data are gathered and manipulation of the subject or the subject's environment that are performed for research purposes.
- Interaction: includes communication or interpersonal contact between investigator and subject.
- Identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- Private Information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information has been provided for a specific purpose by an individual and which the individual can reasonable expect will not be made public (for example, a medical record).



OUSD(P&R) Conducted Human Research Protection Program Approval Process



CDO: Deputy Assistant Secretary of Defense (DASD) for Force Health Protection & Readiness (FHP&R) has overall responsibility for establishing policy and ensuring compliance in OUSD(P&R) HRPP

CPM: Component Program Manager is responsible for the routine management of the CDO's headquarters' office and HRPP

IO: the individual acting in an authorized capacity on behalf of the institutional & with an understanding of the institution's responsibilities under the Assurance

IRB: Institutional Review Board established for the purposes of reviewing research to ensure the protection of human subjects.

EDO: an individual who is authorized to determine if activity is research and make determinations if research is exempt from regulations.

PM: an individual who is authorized to coordinate reviews of human subject research

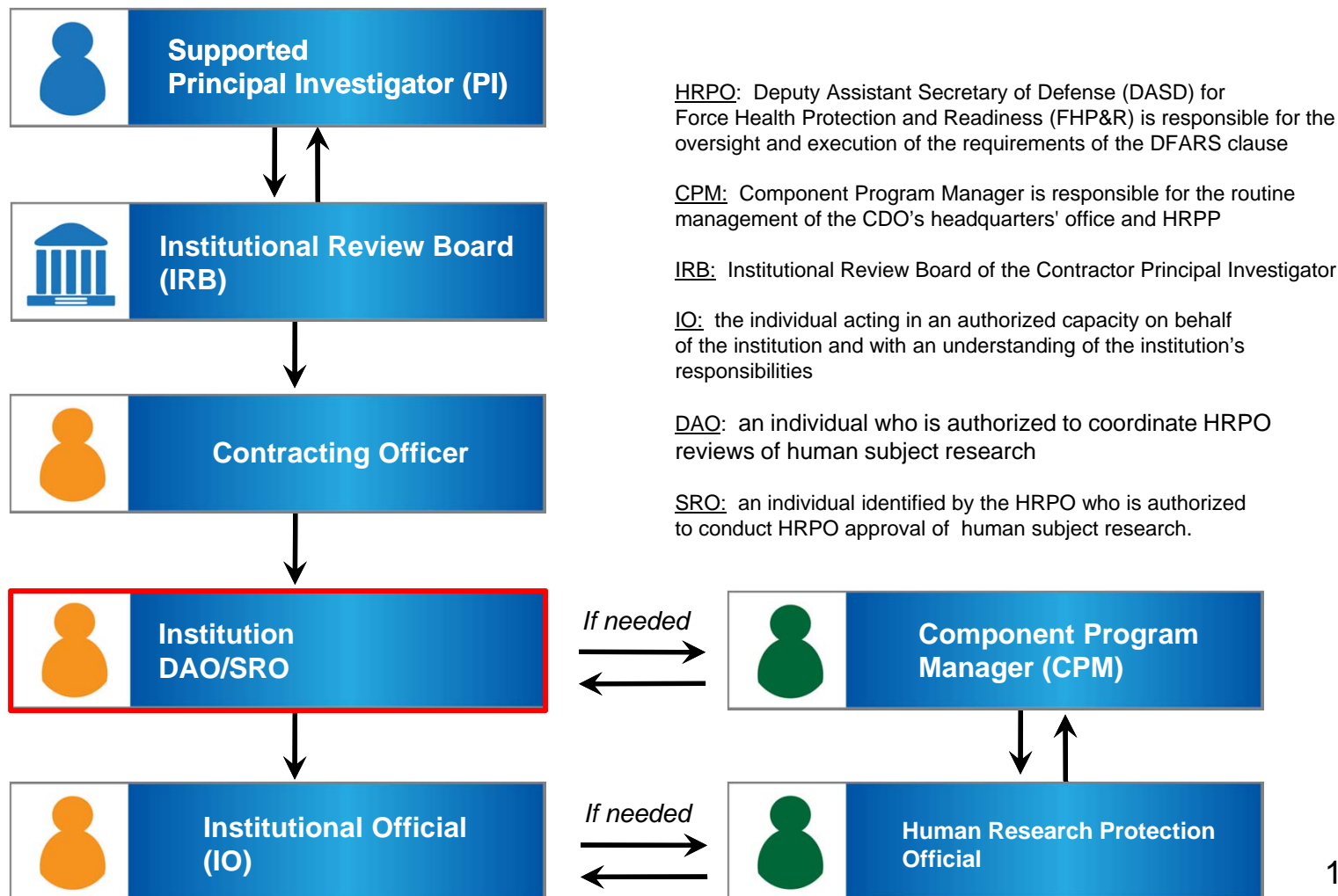


How do we Map DFAR to HRPP?

- Any DoD component sponsoring research involving human subjects:
 - (a) Is responsible for oversight of compliance with 32 CFR Part 219, Protection of Human Subjects; and
 - (b) Must have a [Human Research Protection Official](#) (HRPO), as defined in the clause at **(252) 235-7004**, Protection of Human Subjects, and identified in P&R's Human Research Protection Management Plan.
- For the OUSD(P&R), this person is the:
 - Component Designated Official – DASD(FHP&R)
 - Responsibilities of the HRPO may be delegated as described in the OUSD(P&R) Management Plan.



OUSD(P&R) Supported Human Research Protection Program Approval Process



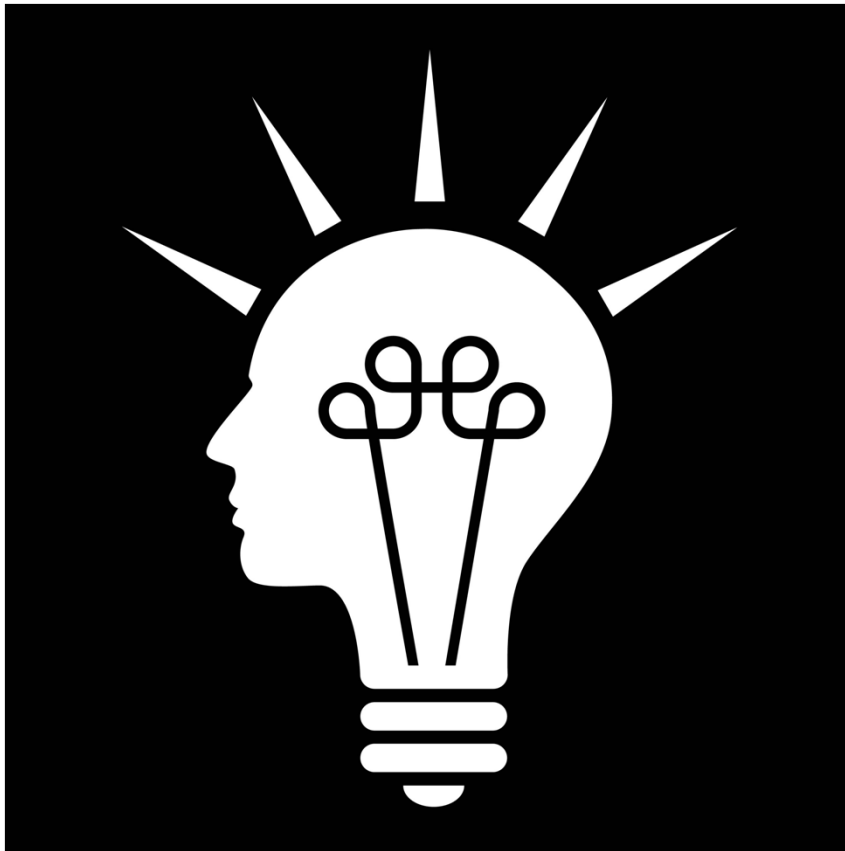


Before Expending Funds on Research

- The Contractor shall not expend funding on research involving human subjects until receiving notification from the Contracting Officer that:
 - The HRPO has approved the assurance and the protocol as appropriate for the research under the Statement of Work (non-exempt research); or
 - The HRPO has accepted documentation that the proposed human research meets exemption criteria in 32 CFR 219.101(b) (exempt research).
- The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.



Points to Remember....



- If you are unsure whether a project is research involving human subjects, contact the local Institution Human Research Protection Program for guidance.
- The Contracting Officer **cannot** determine whether the activity is exempt from Human Subject Research requirements. If the activity appears to be human subject research, it must be submitted to the Institution Human Research Protection Program for review.



Local HRPP Program Managers

Equal Opportunity (EO)	
	Defense Equal Opportunity Management Institute (DEOMI) Contact: 321.494.2676
Department of Defense Education Activity (DoDEA)	
	Contact: 703.588.3175
Military Community & Family Policy (MC&FP)	
	Contact: 703.697.7191
Office of the Assistant Secretary of Defense for Health Affairs (HA)	
	TRICARE Management Activity (TMA) Contact: 703.681.1135
	Defense Centers of Excellence (DCoE) Contact: 301.295.2616
	Uniformed Services University of the Health Sciences (USUHS) Contact: SRO/IRB: 301.295.3836 or 301.295.8999
Office of the Assistant Secretary of Defense for Reserve Affairs (RA)	
	Contact: 703.693.2296
Defense Human Resource Activities (DHRA)	
	Joint Advertising, Market Research & Studies (JAMRS)
	Defense Manpower Data Center
	Civilian Personnel Management Service (CPMS)
	Contact: 831.583.4076 or 703.696.7178
	Defense Personnel Security Research (PERSEREC)
	Contact: 831.657.3016

For other contracts in the Office of the Secretary of Defense, you may contact the Human Research Protection Office:

R2O2@tma.osd.mil